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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/248,158 02/09/99 YUAN

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EXAMINER

HM12/0509

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GARCIA, M

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/248,158

Applicant(s)

Yuan et al

Examiner

Maurie E. Garcia, Ph. D.

Art Unit

1627

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 20, 2001

2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1 and 3-28 is/are pending in the application

4a) Of the above, claim(s) 11-18 and 20-28 is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 3-10, and 19 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other:

DETAILED ACTION

1. The Response filed on February 20, 2001 is acknowledged. Claims 29-46 were cancelled in this amendment. This action is also responsive to the Response filed November 27, 2000. In this amendment, claims 1, 4 and 8 were amended and claim 2 was cancelled (also claims 29-46 were added). Therefore, currently claims 1 and 3-28 are pending.
2. Please note that claims 21-28 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Claims 11-18 and 20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected species. Election was made without traverse in Paper No. 9.
3. Therefore, claims 1, 3-10 and 19 are examined on the merits in this action.

Withdrawn Rejections

4. The rejection under 35 U.S.C. 102(b) over Schlenoff is withdrawn in view of applicant's amendments to the claims.

Sequence Compliance

5. The examiner acknowledges and thanks applicant for complying with the requirements of 37 CFR 1.821 through 1.825 with the submission of July 25, 2000.

Maintained Rejections
Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term “generally” in claim 1 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what the metes and bounds of “generally not stimulated” would be (i.e. how “not stimulated” is “generally not stimulated?”).

B. The terminology “distinct from” in claim 1 is a relative phrase which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Again, the metes and bounds of “distinct from” are unclear (i.e. how is the distinction determined?).

Response to Arguments

8. Applicant's arguments filed November 27, 2000 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

9. Applicants argue that the terms "generally" and "distinct from" are definite. However, the examiner maintains that the terms are relative terms, which render the claims indefinite. Applicants cite a dictionary giving the definitions of the terms (see Response, page 4). The question at hand is not what the terms mean in a literal sense but the fact that they are relative terms. This terminology simply does not provide a standard for ascertaining the requisite degree applicant intends. As stated above, for claim 1, it is unclear how "not stimulated" is "generally not stimulated". For claim 2, again, the method for determining the distinctness is not set forth.

10. With respect to terms such as "essentially", it is noted that these have been found to comply with 35 USC, second paragraph, but only because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to understand the clear meaning of such terms (See MPEP 2173.05(b), B). This is not the situation in the instant case for the reasons set forth above. Also, applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Moreover, although the claims are interpreted in light of the specification, limitations from

the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Maintained Rejections
Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 1, 3-10 and 19 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kasila et al (US 5,972,595).

Kasila et al disclose a method for measuring enzyme activity using a solid support coated with a hydrophobic layer (see column 2, lines 10-23). Specifically, the solid supports are 96-well FlashplatesTM (see definition, column 2, lines 48-50) coated with an artificial lipid layer in various ways (see, for example, column 4, lines 25-38 and column 5, line 63 through column 6, line 22). Enzyme substrates are bound via hydrophobic interactions within the lipid layer (column 3, lines 26-39). The biochemical transformation of the bound substrate causes a cleavage of a portion of the molecule, thus rendering it hydrophilic (see patented claims, especially claim 1). The hydrophilic portion is washed away, thus reducing the level of scintillation (see, for example, column 5, lines 36-60). The assay of Kasila et al can be used to

study various enzymes and is designed to study them in high-throughput fashion
(column 6, lines 24-60).

Response to Amendment/Arguments

13. The declaration filed on November 27, 2000 under 37 CFR 1.131 has been considered but is ineffective to overcome the Kasila reference for several reasons. These are set forth below.

14. First, applicant has elected the species of kinase catalyzed reactions for examination (see Paper No. 9, page 4). The declaration deals almost exclusively with a *different* species, namely part of the reaction cascade for the sequential synthesis UDP-NAcMur-pentapeptide. The claims drawn to this species have been withdrawn from consideration and are not currently under examination. Specific data is not present in the declaration for any kinase catalyzed reactions. Thus, the evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Kasila reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

15. Additionally, the Kasila reference contains the disclosure of various enzyme assays (see Abstract, patented claims and examples). A reference which discloses several species of a claimed genus can be overcome directly under 37 CFR 1.131 *only* by a showing that the applicant completed, prior to the date of the reference, all of the species shown in the reference. *In re Stempel*, 241 F.2d 755, 113 USPQ 77 (CCPA 1957).

16. The test is whether the facts set out in the affidavit are such as would persuade one skilled in the art that the applicant possessed so much of the invention as is shown in the reference *In re Schaub*, 537 F.2d 509, 190 USPQ 324 (CCPA 1976). It is the examiner's position that this is *not* the situation in the instant case. As stated above, there is no specific data for kinase catalyzed reactions, just a general assertion (on page 10 of the instant declaration). See MPEP 715.07: Vague and general statements in broad terms about what the exhibits describe along with a general assertion that the exhibits describe a reduction to practice "amounts essentially to mere pleading, unsupported by proof or a showing of facts" and, thus, does not satisfy the requirements of 37 CFR 1.131(b) *In re Borkowski*, 505 F.2d 713, 184 USPQ 29 (CCPA 1974).

17. Lastly, the Kasila reference is a U.S. patent that claims the rejected invention (see patented claims 1-8 and 13-18). An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the patent is claiming the same patentable invention, see MPEP § 2306. The patent can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings.

***New Rejections – Necessitated by amendment
Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1, 3, 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlenoff (US 5,466,930; Ref. No. 8 on PTO-1449).

Schlenoff teaches “a scintillator for adsorbing and concentrating radioactive ions” that comprises a “solid scintillator and an ionic layer in the surface of and in contact with the solid scintillator” (see Abstract). The scintillating material is a doped plastic such as doped polystyrene (see column 3, lines 27-45 and column 4, lines 25-31). Either a negatively-charged layer or a positively-charged layer is formed on the

surface of the scintillating material (see columns 5-6) and radioactive ions of opposite charge are adsorbed by this modified scintillating surface (see column 1, lines 17-32, column 6, lines 53-60 and the Example). In the example, both labeled (capable of scintillation) and unlabeled calcium ions are used.

Schlenoff lacks the specific teaching of using different ions, but does discuss other moieties that could be detected with their method such as ^{14}C and ^{90}Sr (see column 8, lines 8-16, for example). Schlenoff also teaches that “[c]ontaminated surface and ground water and effluents...often contain radioactive particles” which are often negatively or positively charged ions (column 1, lines 17-33). One of ordinary skill would know that water often contains many other dissolved species as well.

Moreover, various ionic species – some radioactive, some not– were well known in the art. It would also be obvious to one of ordinary skill that any neutral (non-charged) species and/or ions of the same charge as the modified surface would not be adsorbed by the surface of Schlenoff. As stated in the patent, the “layer [modified scintillating surface] is composed of any cationic or anionic group that binds oppositely charged radioactive ions that are present in a solution” (column 4, lines 46-54).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to perform the method of Schlenoff with more than one ion present or in the presence of neutral species since such are often present in water samples.

Response to Arguments

21. Applicant's arguments filed November 27, 2000 have been fully considered but are moot in view of the new grounds of rejection set forth above. However, the examiner has addressed following points with respect to applicants arguments directed at the Schlenoff reference as they are pertinent to the new rejection also.

22. Applicant has amended claim 1 to read “A method for analyzing a sample comprising: a) providing a sample containing at least two molecular species, wherein at least one of the molecular species is capable of stimulating scintillation...” (Response, page 2). Applicant asserts that the Schlenoff does not disclose the added limitation of “at least two molecular species”. Applicant argues that “the Schlenoff reference is directed only to a method for determining whether a single type of molecular species – radioactive ions – are present in the solution” (Response, page 5).

23. However, there is nothing in the instant claims as amended that indicates that more than one *type* of molecular species is present, just that the sample contains at least two molecular species, one of which having a binding interaction that is distinct from the remainder of the species. Thus, it is the examiner's interpretation that the sample could contain a variety of ions (same type of molecular species) and as long as they were different ions, they would read on the instant claim's “at least two molecular species”. It is noted that “molecular species” is defined in the instant specification on page 8, line 23 through page 9, line 3. The new rejection above recognizes that Schlenoff exemplifies a sample containing

only one cation (calcium) but states that using different ions in the method of Schlenoff would be prima facie obvious to one of ordinary skill.

Status of Claims/Conclusion

24. No claims are allowed.

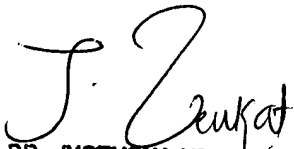
25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703)

308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Maurie E. Garcia, Ph.D.
May 4, 2001